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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,352	06/23/2003	Finn C. Lundsgaard	C12012/129181	1705
7590 BRYAN CAVE LLP 33rd Floor 1290 Avenue of the Americas New York, NY 10104-3300		06/19/2007	EXAMINER GORDON, BRIAN R	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 06/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,352	<b>Applicant(s)</b> LUNDSGAARD ET AL.	
	<b>Examiner</b> Brian R. Gordon	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4-5-07.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed April 5, 2007 have been fully considered but they are not persuasive. Applicant has amended the claims in manner such that new matter has been added which the specification does not provide adequate support of such. The claims now recite each compartment comprising two positions for securing a test device. While specification is supportive of providing a cassette 4 having multiple compartments 12 or 12' there is no support for each of those compartments further having two positions or locations therein. Applicant asserts such amendment is supported by a number of specified passages as well as figures 2D and 2G. The passages do not mention a compartment having two positions therein. Further more figures 2D and 2G are not illustrative of a compartment, but show the test device/cuvette in a position outside the cassette/holder (outside the compartment 12). The term "securing" or any variation thereof cannot be found in the specification more so mentioned in terms as being related to the "two positions". There are no such two positions or first and second positions as claimed. The only referencing to positioning observed by the examiner is that mentioned when describing how the device is intended to operate. That being initially with multiple compartments of the cassette including a cuvette (test device). The cuvettes remain closed off or unexposed to the ambience until each cuvette is rotated to a operational position where an opening exists and when at that position the cuvettes are removed and loaded with a sample and tested therein. After testing, the cuvette 14 is returned via opening back to the compartment in the

cassette and the cassette is further rotated to the next compartment and the process is repeated for each compartment/cuvette until all of the cuvettes have been employed to test a respective sample.

Claim 18 has been amended to recite: loading the sample of the physiological liquid into a test device arranged in the compartment of the holder accessible from the ambience. As stated above the test device/cuvette is removed from the compartment of the holder before the sample is loaded and tested. There is no support for loading the sample in the test device while the test device is in the compartment. How can one load the test device as claimed when the entry port would not be exposed. Furthermore applicant's specification contradicts the claim (see page 27, line 19+ and figures 2D-2G). The cuvette is removed from the cassette and the sample is loaded and tested therein at entry position 14. Claim 18 does not adequately describe the method as disclosed in the specification hence the claims are not commensurate in scope.

Furthermore in relevance to claim 18, applicant asserts (page 14 of arguments):

Claim 18, as amended, recites "loading, to an unused test device arranged in the compartment accessible from the ambience, the sample of the physiological liquid."

The claim does not include such a step as asserted nor mention the classification of a test device. Such argument is not commensurate in scope with that to the claims. The specification does not provide a definition of at what point or what constitutes a device as being classified as used. It appears that a test device is considered "used" only after a sample has been tested in the device. Before the testing occurs the device may be considered unused. Therefore in view of such, even if claim 18 was directed to an

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unused test device in an compartment, Fanning would still be considered to meet the limitation as argued.

In view of such the previous rejection in relevance is hereby maintained.

Due to the inclusion of new matter the art rejection of the apparatus claims has been withdrawn.

### ***Specification***

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Interpretations***

3. As to claim 11, the liquid sample path and filter are mentioned in reference to sample entry port, but are not positively claimed as elements of the device. The claim should be amended to reflect such for the sample path and filter are elements linked to the port and chamber.

### ***Claim Rejections - 35 USC § 102***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Fanning et al. US 5,965,090.

Fanning et al. disclose an automatic sample testing machine for testing samples stored in test cards. The machine has a test sample positioning system for moving a

tray containing a plurality of test sample cards and fluid receptacles among various stations in the machine.

The device processes test cards 28 (testing devices). The device also comprises a carousel incubation station 600. The carousel 604 is housed in an enclosure that is maintained at an appropriate incubation temperature for the particular assay, for example, 35 degrees C. The enclosure is partially broken away in FIGS. 1 and 2 in order to show the carousel 604. The carousel 604 is rotated by a drive system 612 in synchronism with the movement of the boat 22 over the rear of the base pan 26 by the test sample positioning system 100, so as to place the next slot in the carousel 604 in line with the slot 602 opposite the next card in the cassette 26. As seen in the Figures the carousel is comprised of an outer housing and further includes an inner tubular member (holder member) with structural fins extending therefrom outward to an outer housing wall to form slots (compartments).

As the cards 28 are being incubated in the incubation station 600, the cards are periodically, sequentially pushed out of the slots of the carousel 604 at the top of the carousel 604, one at a time, by a reciprocating rack and pinion driver 620 and an associated stepper motor. The cards 28 are moved by an optical scanner card transport station 700 (moving device) past a fluorescence and transmittance optics station 800 (measuring/ detection station) having a transmittance substation 802 and a fluorescence substation 804 (column 8, lines 47-55).

Referring to FIG. 26, in a preferred embodiment a stand-alone cassette identification station 80 is provided to facilitate the processing of the cards 28 by the

machine 20. The station 80 consists of a computer terminal having a monitor 84 and attached keyboard 86 and bar code reader 88. A conventional host CPU and memory are contained in the station 80, which are not shown. The host CPU runs a menu-driven software program that prompts a technician to enter patient or sample information that is to be associated with each of the cards 28. The station 90 has a data port allowing it to communicate with the machine 20 or another computer (col. 21, line 56-65).

The pipetting station 300 includes the pipette 302 (probe) to transfer test samples.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, Telework Thurs., 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



brg

**BRIAN R. GORDON**  
**PRIMARY EXAMINER**

Brian R Gordon  
Primary Examiner  
Art Unit 1743